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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,775	03/20/2001	Frederic DeSavage	GENENT.057CP2	2421

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/27/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/813,775

Applicant(s)

DESAUVAGE ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claims 26 and 27 are improper dependent claims because the claim cites an antibody, but also cites being dependent from claim 24, which is a chimeric molecule; claim 33 is improper dependent claim because the claim cites using antagonist, but also cites being dependent from 31, which is related to CHEPO polypeptide or an agonist. To advance prosecution, claims 26 and 27 are read as being dependent from claim 25, and claim 33 is read as being dependent from claim 32.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:
 - I. Claims 1-15, drawn to a nucleic acid comprising or related to SEQ ID NO:3 or a DNA encoding a CHEPO polypeptide; a vector comprising the nucleic acid; a host cell; a method of producing a CHEPO polypeptide, classified in class 536, subclass 23.1, and class 435, subclasses 320.1 and 325.
 - II. Claims 16-24, 30 and 34-41, drawn to a CHEPO polypeptide comprising or related to SEQ ID NO:2, a variant of CHEPO polypeptide, a chimeric molecule comprising a CHEPO polypeptide fused to a heterologous amino acid sequence, or a composition comprising the CHEPO polypeptide, classified in class 530, subclasses 300 and 350, and class 435, subclass 69.7.
 - III. Claims 25-30, drawn to an antibody specific binds to a CHEPO polypeptide, an agonist or antagonist of a CHEPO polypeptide, where the structure of agonist or antagonist is not defined, classified in class 424, subclass 130.1.

IV. Claim 31, drawn to a method of inducing erythropoiesis in a mammal, comprising administering a CHEPO polypeptide, classified in class 530, subclasses 300 and 350.

V. Claim 31, drawn to a method of inducing erythropoiesis in a mammal, comprising administering an agonist of CHEPO polypeptide, classified in class 530, subclasses 300 and 350.

VI. Claims 32-33, drawn to a method of inhibiting erythropoiesis in a mammal, comprising administering an antagonist of CHEPO polypeptide, wherein the antagonist can be an anti-CHEPO antibody, classified in class 424, subclass 130.1.

VII. Claims 42-44, drawn to a method of stimulating the proliferation of cells expressing EPO receptor, comprising contacting the cells with a CHEPO polypeptide or a CHEPO immunoadhesion, classified in class 530, subclasses 300 and 350, and 424, subclass 130.1.

Should Invention II be elected, applicant is required to select one amino acid sequence for a variant of CHEPO polypeptide from claim 34 or 35. Each peptide has different chemical property and produces different effect, thus, is a distinct peptide. This is not species election.

2. The inventions are distinct, each from the other because of the following reasons:

The polynucleotides of Invention I are related to the polypeptides of Invention II because the polynucleotides encode the claimed peptides. The inventions are distinct because they are physically and functionally distinct chemical entities, and the peptide products can be made by another and materially different process, such as synthetic peptide synthesis or purification from natural source. Further, the polynucleotides may be used for process other than the production of the peptides, such as nucleotide hybridization assay.

The method of Invention I and the polypeptides of Invention II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptides as claimed can be isolated from its natural source or made by chemical peptide synthesis.

The products of Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a nucleic acid and an antibody, which are patentably distinct each from the other because they are physically and functionally distinct chemical entities and also have different utilities. For example, nucleic acid can be used for making probes in northern or southern hybridization, and antibody can be used for western blotting.

The polypeptide of Invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibody. The inventions are distinct because they are physically and functionally distinct chemical entities and because the polypeptide can be used in another and materially different process from the use for production of the antibody such as to assay or purify the cognate receptor of the protein or in assays for the identification of agonists or antagonists of the receptor protein.

The product of Invention I is distinct from the methods of Inventions IV-VII because the product of Invention I can be neither made by nor used in the methods of IV-VII.

The methods of Inventions I and IV-VII are patentably distinct each from the other because they have different method steps, utilize different materials and produce different results.

The product of Invention II and the methods of Inventions IV and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions IV and VII are alternative processes of use of the product of Invention II.

The product of Invention II is distinct from the methods of Inventions V and VI because the product of Invention II can be neither made by nor used in the methods of V and VI.

The product of Invention III and the methods of Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions V and VI are alternative processes of use of the product of Invention III.

The product of Invention III is distinct from the methods of Inventions I, IV and VII because the product of Invention III can be neither made by nor used in the methods of I, IV and VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent

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subject matter, and because each invention requires different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

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September 26, 2002


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800